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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/807,223 | 06/13/2001 | Izumu Saito | Q63988 | 5950 |

7590 07/28/2003

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EXAMINER

HILL, MYRON G

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1648

DATE MAILED: 07/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/807,223

Applicant(s)

SAITO ET AL.

Examiner

Myron G. Hill

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1- 12 and 21- 42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1- 12 and 21- 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This action is in response to paper# 14, filed 21 April 2003.

Claims 1- 12 and 21- 42 are under consideration in this action.

Objections Withdrawn

Claim Objections

Claim 1 was objected to because of the following informalities: The claim ends in a comma but should end in a period. Appropriate correction was required.

This has been corrected. Objection withdrawn.

Rejections Withdrawn

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 5, 22, 28- 32, and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear that the recited elements all constitute a promoter or if promoter is meant to be something other than what is normally known in the art. Splice acceptor sites and poly-A sites are not normally considered part of a promoter.

Applicant has amended the claims to clarify the list of features and explained inclusion of splice acceptor. Rejection withdrawn.

Claim Rejections - 35 USC § 103

Claims 1- 12 and 21- 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hardy (WO 97/32481) and Wahl et al. (WO 92/15694).

The claims are drawn to a cell that expresses Cre recombinase in the presence of recombinase FLP in a FLP- dependent manner.

Applicant argues that the claimed invention is extremely useful in a helper dependent adenovirus vector system and references locations in the disclosure that teach the construction of the claimed cells and methods to make recombinant virus, as well as that the novelty is particularly in the expression of Cre in a regulated manner and thus is useful in the previously mentioned helper dependent adenovirus system. Applicant also argues that Hardy does not teach the invention, that Hardy does not teach expression of Cre in a controlled manner, and that Wahl does not teach expression of Cre. Finally, Applicant concludes that the cells are novel in that they only express Cre when desired and express E1A and this is useful in making adenovirus using a helper virus and this characteristic of the claimed invention is not taught or even suggested by Hardy or Wahl.

Applicant's arguments have been fully considered and not found persuasive.

Applicant is arguing limitations that are not in the claims and intended uses. The claims are drawn to a cell that expresses Cre recombinase in the presence of

Art Unit: 1648

recombinase FLP in a FLP- dependent manner with dependent claims adding the cell also produces E1A. The cells of Hardy are 293 cells and those are notoriously well known in the art to produce E1A.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

From the discussion (in particular page 14, lines 26- 31), Hardy discloses that it is not advantageous to grow recombinant virus in a cell expressing Cre all the time. Hardy uses a 293 cell line that does not produce Cre in parts 1 and 2 of the method to produce recombinant adenovirus and use a 293 cell line that expresses Cre in the part 3 of the method. One of skill in the art would know that gene expression can be regulated. In order to control Cre expression one of skill in the art would be able to search for methods of regulation of gene expression and would find the system of Wahl and would be motivated to combine them because Wahl teaches that the FLP recombinase teaches can be used to regulate gene expression. Hardy already teaches a cell line that expresses E1A and Cre that is useful in to produce recombinant adenovirus in a helper-dependent manner.

Wahl is provided to supply a gene regulation system as indicated, Wahl does not need to teach adenovirus to supply a non-deficiency of Hardy.

The rejection is maintained.

Conclusion

No claim is allowed.

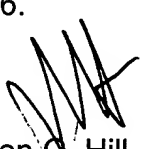
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4247. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Myron G. Hill
Patent Examiner
July 24, 2003


JAMES HOUSEL 7/27/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600